



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/761,185

01/20/2004

Austin W. Mutchler

DEP5031

2594

27777 7590 07/28/2008
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

07/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/761,185
Filing Date: January 20, 2004
Appellant(s): MUTCHLER, AUSTIN W.

Stephen J. Manich
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/11/2008 appealing from the Office action mailed 01/08/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

Claims 1-5, 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ackeret et al. (US Pat. 6,319,253 B1).

Ackeret et al. disclose an intramedullary nail (Fig. 1, ref. 1a) (abstract) for use with a first fastener and a second fastener for use in orthopaedic surgery, said nail comprising a body (Fig. 1, ref. 1a) defining a longitudinal axis thereof, the body having a continuous edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5) therethrough, the continuous edge having opposed straight parts (Fig. 1a, near

ref. 6) and curved parts (Fig. 1a, refs. 4 and 5), the aperture having a first portion defined by the opposed straight parts of the continuous edge (Fig. 1) for cooperation with the first fastener to provide dynamic fixation and having two spaced cylindrical end portions (Fig. 1a, end portions near refs. 4 and 5) defined by the curved parts of the continuous edge for cooperation with the second fastener to provide static fixation (Fig. 1a), the first portion of the aperture lying between the cylindrical portions of the aperture (Fig. 1a), the cylindrical portions of the aperture having widths greater than the distance between the opposed straight parts of the continuous edge defining the first portion of the aperture (Fig. 1a), the aperture being symmetrical about a longitudinal axis extending between the cylindrical portions and between the straight parts of the edge (Fig. 1a). Regarding the symmetry of the aperture, if one considers the axis of ref. 3 in Fig. 1a as the "longitudinal axis" of the claims and one rotates the nail shown by ninety degrees, then the longitudinal axis will split the entire slot in two symmetrical portions, one on the left and one on the right. By rotating the entire nail shown in Fig. 1a by ninety degrees, the slot is bilaterally symmetrical about the longitudinal axis of ref. 3.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,319,253 B1	ACKERET ET AL.	11-2001
5,814,047	EMILIO ET AL.	9-1998
2003/0195515 A1	SOHNGEN	10-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ackeret et al. (US Pat. 6,319,253 B1).

Ackeret et al. disclose an intramedullary nail (Fig. 1, ref. 1a) (abstract) for use with a first fastener and a second fastener for use in orthopaedic surgery, said nail comprising a body (Fig. 1, ref. 1a) defining a longitudinal axis thereof, the body having a continuous edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5) therethrough, the continuous edge having opposed straight parts (Fig. 1a, near ref. 6) and curved parts (Fig. 1a, refs. 4 and 5), the aperture having a first portion defined by the opposed straight parts of the continuous edge (Fig. 1) for cooperation with the first fastener to provide dynamic fixation and having two spaced cylindrical end portions (Fig. 1a, end portions near refs. 4 and 5) defined by the curved parts of the continuous edge for cooperation with the second fastener to provide static fixation (Fig. 1a), the first portion of the aperture lying between the cylindrical portions of the aperture (Fig. 1a), the cylindrical portions of the aperture having widths greater than the distance between the opposed straight parts of the continuous edge defining the first portion of the aperture (Fig. 1a), the aperture being symmetrical about a longitudinal axis extending between the cylindrical portions and between the straight parts of the edge (Fig. 1a). Regarding the symmetry of the aperture, if one considers the axis of ref. 3 in Fig. 1a as the "longitudinal axis" of the claims and one rotates the nail shown by ninety degrees, then the longitudinal axis will split the entire slot in two symmetrical portions,

one on the left and one on the right. By rotating the entire nail shown in Fig. 1a by ninety degrees, the slot is bilaterally symmetrical about the longitudinal axis of ref. 3. The opposed straight parts of the continuous edge define a rectangular central section (Fig. 1a). The cylindrical end sections are adapted to matingly fit with the first fastener (Fig. 2a). The cylindrical end sections are adapted to one of slidable fit and threadable fit with the first fastener (Fig. 2a). The aperture is adapted to provide for a slidable fit of the first fastener with said body along the longitudinal axis of said body (Fig. 2a). The aperture defines a slot axis thereof, the slot axis being perpendicular to the longitudinal axis of said body (Fig. 1a).

With regard to claims 11-20 and 22-32, Ackeret et al. disclose a kit for use in orthopaedic surgery, the kit comprising: a first fastener (Fig. 2a, ref. 11) comprising a shank (Fig. 2a) having maximum outer diameter; a second fastener (Fig. 2a, ref. 10) comprising a shank having a maximum outer diameter (Fig. 2a).

With regard to claim 21, Ackeret et al. disclose a method for use in orthopaedic surgery comprising: providing an orthopaedic surgery kit including a first fastener (Fig. 2a, ref. 11) comprising a shank (Fig. 2a) having a maximum outer diameter (Fig. 2a), a second fastener (Fig. 2a, ref. 10) comprising a shank (Fig. 2a) having a maximum outer diameter greater than the maximum outer diameter of the first fastener (Fig. 2a), and an intramedullary nail (Fig. 2b, ref. 1) having a body defining a longitudinal axis thereof (Fig. 2a), the body having an edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5) therethrough, the aperture having a first portion (Fig. 1a) for cooperation with the first fastener to provide dynamic fixation and having a

second portion (Fig. 1a) extending from and connected to the first portion for cooperation with the second fastener to provide static fixation, the edge continuing around and defining both the first and second portions of the aperture (Fig. 1a), the aperture being symmetrical about a longitudinal axis extending between the cylindrical portions and between the straight parts of the edge (Fig. 1a); cutting an incision in the patient (since this must occur prior to inserting the intramedullary nail in the body); preparing a bone cavity (since the intramedullary canal must have a cavity in which it is placed within the body); inserting the nail into the cavity; choosing one of static fixation (column 1, lines 57-67, since the device is to be statically placed within the bone, e.g. “contribute to prevent longitudinal displacement of the nail”) and dynamic fixation for the surgery; selecting one of the first fastener and the second fastener based on the choice of one of static fixation (Fig. 2a) and dynamic fixation for the surgery; and securing the chosen one of the first fastener and the second fastener into the nail wherein the maximum outer diameter of the second fastener is greater than the width of the first portion of the aperture (Fig. 2a), and wherein the first fastener is secured between the straight parallel parts of the edge in the first portion of the aperture if dynamic fixation is chosen and the second fastener is secured in the second portion of the aperture if static fixation is chosen (Fig. 2a, 2b).

Claims 8, 11-16, 18, 20, 22-27, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Sohngen (US Pub. 2003/0195515 A1).

Ackeret et al. disclose the claimed invention except for the intramedullary nail further comprising a resorbable component received within one of the cylindrical portions of the aperture and engaging the parts of the edge defining the cylindrical portion of the aperture; and the maximum outer diameter of the shank of the first fastener being less than the distance between the first substantially parallel parts of the edge defining the first portion of the aperture

Sohnngen discloses an intramedullary nail (Fig. 2) that comprises a resorbable component (Fig. 2, ref. 50)(paragraph 0045) that is found within a cylindrical portion of an aperture (Fig. 2, aperture near ref. 56). The maximum outer diameter of the shank (Fig. 14, shank of ref. 32) of the first fastener is less than the distance between the first substantially parallel parts (Fig. 8, parallel portions of ref. 56) of the edge defining the first portion (since this must be the case in order to allow dynamization to occur). The aperture, shank and the resorbable material are used for dynamization, in order to decrease the load carried by the fasteners and nail member and transfer the load to the fracture as the fracture heals (paragraph 0045).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have utilized a resorbable component and the relative dimensions of the slot and fastener as taught by Sohnngen with the intramedullary nail of Ackeret et al., in order to make the implant dynamic, which will work to decrease the load carried by the fasteners and nail member and transfer the load to the fracture as the fracture heals (paragraph 0045).

With regard to claim 32, Ackeret et al. in view of Sohngen disclose the claimed invention except for the third fastener. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the kit of Ackeret et al. with a third fastener, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Emilio et al. (US Pat. 5,814,047).

Ackeret et al. disclose the claimed invention except for the body adjacent the first mentioned cylindrical end defines internal threads therein; and wherein said body adjacent the second cylindrical end defines internal threads therein. The body comprises internal threads formed in the body adjacent the aperture; and wherein said resorbable component comprises external threads formed thereon for cooperation with internal threads of said body.

Emilio et al. disclose the body adjacent the first mentioned cylindrical end (Fig. 12, 130) defining internal threads therein (Fig. 12, 131) and the body adjacent the second cylindrical end (Fig. 12, 140) defining internal threads therein (Fig. 12, 141) (see also Fig. 9), for engagement and guiding of screws (column 5, lines 19-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the intramedullary nail of Ackeret et al. with the body adjacent the first mentioned cylindrical end defining internal threads therein

and the body adjacent the second cylindrical end defining internal threads therein, for engagement and guiding of screws (column 5, lines 19-24).

Claims 9, 17, 19, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Sohngen (US Pub. 2003/0195515 A1) in view of Emilio et al. (US Pat. 5,814,047).

Ackeret et al. in view of Sohngen disclose the claimed invention except for the resorbable component comprising external threads formed thereon.

Emilio et al disclose the body adjacent the first mentioned cylindrical end (Fig. 12, 130) defining threads therein (Fig. 12, 131) and the body adjacent the second cylindrical end (Fig. 12, 140) defining internal threads therein (Fig. 12, 141) (see also Fig. 9), for engagement and guiding of screws (column 5, lines 19-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the intramedullary nail of Ackert et al. in view of Sohngen with threads in the in the body (e.g. the resorbable component) adjacent the first and second cylindrical ends, for engagement and guiding of screws (column 5, lines 19-24).

(10) Response to Argument

Appellant states on page 8, "Locking hole 1 (including slot 6) of the Ackeret embodiments is accordingly shaped to accommodate spiral blades. These Ackeret locking slots are therefore not symmetrical. (see, e.g. FIG. 1a, 3b, 4a, 5a). Nor does it

appear that the Ackeret locking slots would be capable of accommodating spiral blades if the shape was changed to make the slots symmetrical."

The examiner respectfully disagrees with the Appellant that the slots are not symmetrical. The slots are symmetrical if viewed from a different angle other than the one shown in Fig. 1a. If one considers the axis of ref. 3 in Fig. 1a as the "longitudinal axis" of the claims and one rotates the nail shown by ninety degrees, then the longitudinal axis will split the entire slot in two symmetrical portions, one on the left and one on the right. By rotating the entire nail shown in Fig. 1a by ninety degrees, the slot is bilaterally symmetrical about the longitudinal axis of ref. 3.

Applicant further states on Page 9, "If one of ordinary skill in the art desired to allow for dynamic fixation in Ackeret et al. element 4 of Ackeret et al. (an "elongated passage") would be suitable to accept a suitably sized screw; it would not be necessary to provide a fastener with a maximum outer diameter allowing it to fit within the slot 6 to allow for dynamic fixation in Ackeret et al. Accordingly, no motivation or suggestion is seen in Sohngen to provide a fastener with a maximum outer diameter less than the width of slot 6 in Ackeret et al. and the rejection of Claims 11-16, 18, 20 and 32 under 35 USC §103 is improper."

The examiner respectfully disagrees with the Appellant that there is not motivation to modify the fastener to allow it to fit within the slot. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have utilized a resorbable component and the relative dimensions of the slot and fastener as taught by Sohngen with the intramedullary nail of Ackeret et al., in order to

make the implant dynamic, which will work to decrease the load carried by the fasteners and nail member and transfer the load to the fracture as the fracture heals (Sohngen, paragraph 0045). By modifying the fastener in this manner, the fastener can slide the entire length of the slot and allow for dynamization to occur, which transfers load to the fracture, which promotes healing at the fracture site. Furthermore, if one did not modify the fastener in this manner as taught by Sohngen, then the fastener could not slide the entire length of the slot and dynamization would be hindered and healing at the fracture site would also be hindered.

The above rejections are therefore deemed proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer

exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Art Unit: 3700

Respectfully submitted,

/Jerry Cumberledge/

Examiner, Art Unit 3733

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Frederick R Schmidt/

Director, Technology Center

Conferees:

Todd Manahan

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731

Marc Jimenez

/Marc Jimenez/

TQAS TC 3700